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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/704,054	11/01/2000	Robert D'Amato	9516-039-999	3798

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EXAMINER	
ANDERSON, JAMES D	
ART UNIT	PAPER NUMBER
1629	
MAIL DATE	DELIVERY MODE
05/03/2011	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	09/704,054	D'AMATO, ROBERT	
	Examiner	Art Unit	
	JAMES ANDERSON	1629	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *05 April 2011*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *23,29,73,76 and 77* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *23,29,73,76 and 77* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *4/5/2011*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 4/5/2011 has been entered.

Formal Matters

Claims 23, 29, 73, and 76-77 are pending and under examination.

Applicant has amended the claims in a manner such that they are now in the same condition they were in the claim set filed 6/17/2009. Accordingly, the Examiner is reinstating Vogelsang et al. and Kaplan prior art as set forth in the Final Office Action mailed 8/3/2009.

Response to Arguments

Applicants' arguments, filed 4/5/2011, have been fully considered but they are not deemed to be persuasive. Rejections and/or objections not reiterated from previous office actions are hereby withdrawn. The following rejections and/or objections are either reiterated or newly applied. They constitute the complete set presently being applied to the instant application.

Information Disclosure Statement

Receipt is acknowledged of the Information Disclosure Statement filed 4/5/2011. The Examiner has considered the references cited therein to the extent that each is a proper citation. Please see the attached USPTO Form 1449.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 23, 29, 73, and 76-77 are rejected under 35 U.S.C. 103(a) as obvious over **Vogelsang et al.** (N. Engl. J. Med., 1992, vol. 326, pages 1055-1058) (Reference C304 in IDS filed 11/7/2007) in view of **Kaplan** (USP No. 5,385,901).

Vogelsang et al. teach administration of thalidomide to patients with chronic graft versus host disease whose primary diagnosis was chronic myelogenous leukemia (21 patients) (Table 1). The reference thus teaches administration to patients "having the blood-borne tumors" as recited in claims 23, 29, and 77 and to patients having "leukemia" as recited in claim 73.

Thalidomide was administered in an initial dose of 200 mg four times a day in adults (800 mg/day) and 3 mg per kg of body weight given four times a day in children (12 mg/kg/day) (page 1056, left column). These doses render obvious the dose ranges recited in the instant claims. For example, 800 mg/day administered to an average human adult is approximately 10 mg/kg/day.

Thalidomide was orally administered, as the authors state that "patients who were unable to take oral medications....were excluded" (page 1055, right column, "Methods") and "Of the 21 patients with high-risk chronic GVHD, 6 were unable to absorb oral medications...these 6 patients were included among the patients judged to have no response" (paragraph bridging pages 1056-1057).

Thalidomide was found to be "safe and effective" for the treatment of chronic graft-versus-host-disease (Abstract).

Vogelsang et al. do not explicitly disclose in what form thalidomide was administered (e.g., capsule, tablet, powder, solution, etc.).

However, Kaplan discloses compounds useful for controlling abnormal concentrations of TNF-α in patients (Abstract). The compounds of the invention include thalidomide (Figures and Examples; Claims). With regard to administration routes and forms, Kaplan et al. teach that the compounds of the invention can be administered **orally** in form of tablets, pills, lozenges, dragees and similar shaped and/or compressed preparations (col. 10, line 61 to col. 11, line 33).

Accordingly, it would have been prima facie obvious to one of ordinary skill in the art at the time of the invention to administer thalidomide to chronic myelogenous leukemia patients having graft-versus-host-disease via any administration known to be useful for such compounds. In this regard, Kaplan et al. teach and motivate one skilled in the art to administer compounds such as thalidomide via well known administration routes. As such, one skilled in the art would have been imbued with at least a reasonable expectation of success in formulating a dosage form of thalidomide for administration to chronic myelogenous leukemia patients having graft-versus-host-disease via the routes and in the dosage form instantly claimed with a reasonable expectation that such administration would be effective to treat graft-versus-host-disease in such patients as evidenced by Vogelsang et al.

The cited prior art teaches, suggests, and motivates orally administering thalidomide to the same patient poplulation(s) recited in the instant claims. As such, that the prior art teaches that such administration treats GVHD whereas the claims recite treating blood-borne tumors (e.g., leukemia) is immaterial to the basis for the rejection. This is because the treatment of blood-borne tumors in the treated patients must necessarily have occurred, whether recognized by Vogelsang et al. or not, because the same active agent was administered to the same patients in the same amounts recited in the instant claims.

The prior art clearly recognized that oral administration to patients with blood-borne tumors (and who were undergoing allogenic bone marrow transplantation) had a therapeutic benefit in such patients at the doses recited in the instant claims, i.e., treatment of chronic graft-versus-host disease. As such, recitation of additional therapeutic benefit, i.e., treatment of the blood-borne tumor per se, does not distinguish the claimed methods from the cited prior art.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to JAMES ANDERSON whose telephone number is (571)272-9038. The examiner can normally be reached on MON-FRI 9:00 am - 5:00 pm EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jeffrey Lundgren can be reached on 571-272-5541. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/James D. Anderson/

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